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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,171	03/10/2004	Dean E. Cropper	CRP002	3497
50571 THE HARRIS I	7590 02/02/201 F IRM		EXAMINER	
922 N STREET	, NW STE . 101		NICHOLSON, KERI JESSICA	
WASHINGTON, DC 20001			ART UNIT	PAPER NUMBER
			3772	
			NOTIFICATION DATE	DELIVERY MODE
			02/02/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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	Application No.	Applicant(s)				
Office Action Comments	10/796,171	CROPPER, DEAN E.				
Office Action Summary	Examiner	Art Unit				
	KERI J. NICHOLSON	3772				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠ Responsive to communication(s) filed on 28 D	ecember 2009					
<i>,</i> —	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
•	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4)⊠ Claim(s) <u>1-29 and 32-40</u> is/are pending in the a	P)⊠ Claim(s) <u>1-29 and 32-40</u> is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-29 and 32-40</u> is/are rejected.						
7) Claim(s) is/are objected to.	′) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9)⊠ The specification is objected to by the Examiner.						
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: <u>copy of PTOI</u>	ite atent Application				

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DETAILED ACTION

This Office action is in response to the amendments and arguments filed December 28, 2009 along with a request for continued examination. Claims 1-3, 5, 6, 10-12, 15-20, 23-29, 32, 34, and 36-40 have been amended; claims 1-29 and 32-40 are currently pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 28, 2009 has been entered.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claims 1-3, 5, 6, 10-12, 15-17, 19, 20, 23-29, 32, 34, are 36-40, as currently amended, recited the limitation "a concentrated, medial <u>and posterior traction</u> member"; however, there is insufficient antecedent basis for the term "posterior traction" in the specification.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 1-3, 5, 6, 10-12, 15-17, 19, 20, 23-29, 32, 34, are 36-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added limitation "posterior traction" is not supported by the original specification such that it is considered new matter. As best can be understood from the specification, there is support for the limitation "medial traction" as well as the limitation "inward traction"; however, this is not sufficient to support "posterior traction" as the terms "medial", "inward", and "posterior" are not synonymous with each other.

5. Claims 2-14, 16-26, 28, 29, and 33-39 are also rejected under 35 U.S.C. 112, first paragraph, for depending from a rejected base claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 7. Claims 1-3, 5-8, 13-17, 19-21, 26-29, 32, 36, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Labour et al. (US Patent 4,445,505).
- 8. Regarding claim 1, Labour discloses a knee orthosis (10) comprising a medial tracking member (36, 38) that operatively fits along a lateral side of, and provides medial traction to, a patella having a patellafemoral articular tissue and a concentrated elastic traction member (80) that operatively fits over, and provides medial and posterior pressure against, a patella, wherein

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the traction member (80) is capable of providing a concentrated compressive force against the patella when in use thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove.

- 9. As for claim 2, note that the pressure provided by the traction member (80) is capable of being applied through an intermittent and progressively increased tightening of the traction member.
- 10. As for claim 3, note that the traction member (80) directly overlays the patella and the medial tracking member so that medial traction can be placed on the patella.
- 11. As for claim 5, note that the traction member (80) is adjustable to increase or decrease an amount of inward pressure.
- 12. As for claim 6, note that the traction member (80) is capable of providing a continuous compressive force against the patella throughout a full range of extension motion of an associated knee.
- 13. As for claim 7, note that the continuous compressive force can be the same throughout the extension motion.
- 14. As for claim 8, note that the continuous compressive force increases throughout the extension motion.
- 15. As for claim 13, note that the members (36, 38) are raised member.
- 16. As for claim 14, note that the traction member (80) comprises an elastic, adjustable strap.
- 17. As for claims 15-21, 26, 32, 36, and 37, note the comments with respect to the claims above.
- 18. As for claim 16, note that the pressure provided by the traction member (80) can be applied through an intermittent and progressively increased tightening of the traction member

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(80) by adjusting the position of the free end of traction member (80) relative to member (92) (Fig. 2).

- 19. As for claim 19, note that the traction member (80) of Labour is capable of being adjusted to increase or decrease an amount of inward pressure.
- 20. As for claims 20 and 21, note that the traction member is capable of providing continuous compressive force against the patella throughout a full range of extension motion of an associated knee, and wherein the continuous compressive force can be substantially the same throughout the extension motion.
- 21. As for claim 26, note that the traction member (80) is an elastic strap.
- 22. As for claims 27-29, note that the device of Labour teaches the recited steps of applying the medial tracking member (36, 38) that operatively fits along a lateral side of, and in doing so providing medial traction to a patella having patellofemoral articular tissue; and applying an concentrated elastic traction member (80) that operatively fits over, and in doing so would provide medial and posterior pressure against, the patella; wherein the inward tracking member (80) would actively provide a compressive force against the patella when in use, thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove.
- 23. As for claim 28, note that if desired by a wearer, when the position of traction member (80) is adjusted, the inward pressure is capable of being applied through an intermittent and progressively increased tightening of the inward tracking member.
- 24. As for claim 29, note that if desired by a wearer, the medial traction applied through the intermittent and progressively increased tightening of the traction member (80) would increasingly stretch lateral patellar connective tissue over time.
- 25. As for claims 32, 36, and 37, note the comments with respect to the claims above.

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26. Claims 1-8, 13- 21, 26- 29, 32-37, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Lehman (US Patent 3,804,084).

- 27. Regarding claim 1, Lehman teaches a medial tracking member (60, 62) operatively fits along a lateral side of, and capable of providing medial traction to, a patella having patellofemoral articular tissue and a concentrated traction member (90) that operatively fits over, and capable of providing medial and posterior pressure against, the patella; wherein the traction member (90) is capable of actively providing a compressive force against the patella when in use, thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove.
- 28. As for claim 2, note that the provided by the traction member (90) is capable of being applied through an intermittent and progressively increased tightening of the traction member.
- 29. As for claim 3, note that the traction member (90) directly overlays the patella and the medial tracking member (60, 62) so that medial traction can be placed on the patella.
- 30. As for claim 4, note that the medial tracking member (60, 62) is adjustable to increase or decrease an amount of medial traction.
- 31. As for claim 5, note that the traction member (90) is adjustable to increase or decrease an amount of inward pressure.
- 32. As for claim 6, note that the traction member (90) is capable of providing a continuous compressive force against the patella throughout a full range of extension motion of an associated knee.
- 33. As for claim 7, note that the continuous compressive force can be the same throughout the extension motion.

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34. As for claim 8, note that the continuous compressive force increases throughout the extension motion.

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- 35. As for claim 13, note that the members (60, 62) are raised member.
- 36. As for claim 14, note that the traction member (90) comprises an elastic, adjustable strap.
- 37. As for claims 15-21 and 26, note the comments with respect to the claims above.
- 38. As for claim 27, note that the device of Lehman has all structure recited in claim 27 with the medial tracking member (60, 62) and a concentrated elastic traction member (90) wrapped and secured around the knee in a manner similar to the manner in which Applicant's medial tracking member and Applicant's traction member are wrapped and secured around a knee; wherein in applying the device taught by Lehman to a wearer, one would perform the steps of applying the medial tracking member (60, 62) that operatively fits along a lateral side of, and in doing so providing medial traction to, a patella having patellofemoral articular tissue; and applying the traction member (90) that operatively fits over, and in doing so would provide medial and posterior pressure against, the patella; wherein the traction member (90) would actively provide a compressive force against the patella when in use, thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove.
- 39. As for claim 28, note that if desired by a wearer, when the position of traction member (90) is adjusted, the inward pressure is capable of being applied through an intermittent and progressively increased tightening of the traction member.
- 40. As for claim 29, note that if desired by a wearer, the medial traction applied through the intermittent and progressively increased tightening of the traction member (90) would increasingly stretch lateral patellar connective tissue over time.

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41. As for claims 32-37, note the medial tracking strap (60, 62), and note the comments with respect to the claims above.

42. As for claim 40, note that Lehman teaches the recited steps.

Claim Rejections - 35 USC § 103

- 43. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 44. Claims 4, 9-12, 18, 22-25, 33-35, and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Labour et al. (US Patent 4,445,505) in view of Cawley et al. (US Patent 6,551,264) and/or Lehman (US Patent 3,804,084).
- 45. Note the comments above for the teaching of Labour et al. Cawley teaches a knee orthosis comprising adjustable medial tracking member (76, 74, 78, 80) (Fig. 1) that operatively fits along a lateral side of, and capable of providing medial traction to a patella having patellofemoral adicular tissue, and teaches the use of polycentric hinge (Fig. 5). Lehman teaches a knee support comprising an adjustable medial tracking member (60, 62) that operatively fits along a lateral side of, and capable of providing medial traction to a patella having patellofemoral adicular tissue. In view of the teachings of Cawley and/or Lehman, it would have been obvious to one ordinary skill in the art at the time the invention was made to modify the device of Labour by providing a polycentric hinge to assist in the motion or bending of the knee, and by providing adjustable medial tracking member in order to adjust the degree of media traction placed on the patella. The provision for a polycentric hinge for a knee brace is well known in the art, and does not provide any unobvious result, and therefore is not patentable

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over prior art as evidenced by the polycentric hinges taught in US Patents 4,781,179 and 4,572,170.

- 46. As for claim 4, note that the medial tracking member (76, 74, 78, 80) of Cawley is adjustable to increase or decrease an amount of medial traction.
- 47. As for claims 9-11 and 22-24, note Figure 5 of Cawley. The provision for a polycentric hinge for a knee brace is well known in the art, and does not provide any unobvious result, and therefore is not patentable over prior art as evidenced by the polycentric hinges taught in US Patents 4,781,179 and 4,572,170.
- 48. As for claims 12 and 25, note the elastic sleeve (12) of Labour, and note the member (44) of Cawley.
- 49. As for claims 18, 33-35, 38, and 39, note the comments with respect to the claims above.
- 50. As for claim 40, note that the device of Labour, Cawley, and/or Lehman, in combination, teaches the recited steps.
- 51. Claims 9-12, 22-25, 38, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lehman (US Patent 3,804,084) in view of Cawley et al. (US Patent 6,551,264).
- 52. Note the comments above for the teaching of Lehman. Cawley teaches a knee orthosis with bicentric hinge (note Fig. 5 of Cawley). In view of this teaching of Cawley, it would have been obvious to one ordinary skill in the art at the time the invention was made to modify the device of Lehman, by providing polycentric hinge to assist in the motion or bending of the knee. The provision for a polycentric hinge for a knee brace is well known in the art, and does not

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provide any unobvious result, and therefore is not patentable over prior art as evidenced by the polycentric hinges taught in US Patents 4,781,179 and 4,572,170.

53. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Labour et al. (US Patent 4,445,505) in view of Lamping et al. (US Patent 6,485,448).

- 54. Note the comments above for the teaching of Labour. Lamping teaches rubber tubing (8) covered with elastic material (9) (Fig. 4; column 3, lines 40-54). In view of the teaching of Lamping, it would have been obvious to one ordinary skill in the art at the time the invention was made to provide this structure for the device of Labour to provide more stable or rigid support for the medial tracking member (36, 38).
- 55. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lehman (US Patent 3,804,084) in view of Lamping et al. (US Patent 6,485,448).
- Note the comments above for the teaching of Lehman. Lamping teaches rubber tubing (8) covered with elastic material (9) (Fig. 4; column 3, lines 40-54). In view of the teaching of Lamping, it would have been obvious to one ordinary skill in the art at the time the invention was made to provide this structure for the device of Lehman to provide more stable or rigid support for the medial tracking member (60, 62).

Response to Arguments

- 57. Applicant's arguments filed December 28, 2009 have been fully considered but they are not persuasive.
- 58. In response to Applicant's summary of the interview held on December 2, 2009, the examiner disagrees with Applicant's statement numbers (3) and (4). With respect to Applicant's

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third statement, the examiner does not recall having made the suggestion to use the term "unobstructed" to define the inward member, and furthermore, the term "unobstructed" would not be supported by the disclosure as originally filed. With respect to Applicant's fourth statement, while Applicant asserted that the term "tracking" would not include the passive capabilities, this was not agreed on by the examiner and it was requested that Applicant provide evidence and support regarding how the term "tracking" would impart any structural limitations on the device.

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- 59. In response to Applicant's note that an interview summary from the examiner for the telephone interview on December 2, 2009, the examiner notes that an interview summary was mailed to Applicant on December 10, 2009 to the address of record for The Harris Firm at 922 N Street, NW STE. 101, Washington, DC 20001. If the address of record is incorrect, it is the applicant's responsibility to notify the Office of any necessary changes. However, an additional copy of the interview summary by the examiner has been attached to this Office action.
- 60. Regarding the Declaration of Christopher Powers, Ph.D., it is noted that it was considered by Examiner Pham in the Office action mailed December 31, 2007. Further, if Applicant wishes to rely on the declaration for support, it should be resubmitted to reflect the current claim amendments. Further, it is noted that the references to Morrison (US Patent 2,858,540) and DiPietro (US Patent 5,649,901) are not relied upon in the current rejections.
- 61. In response to Applicant's and Dr. Powers' arguments that neither Labour nor Lehman teach "a concentrated medial and posterior traction member", the examiner disagrees. In the instant case, both Labour and Lehman teach concentrated elastic traction members which are each capable of providing medial and posterior pressure against a patella of a knee when in use. Because the traction member (80) taught by Labour extends laterally to medially across a patella, it will clearly provide medial traction to the patella as well as apply a compressive force

over the patella towards to posterior of the knee. The traction member (90) taught by Lehman extends from one side of the device to the other across a patella and would be capable of applying medial traction to the patella depending on the orientation of the device or the leg of the user on which the device is worn. It is noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

62. In response to Applicant's assertion that most knee braces the prior art teach a protective nest or opening about the wearer's patella, it is noted that the features or absence of features upon which Applicant relies (i.e., protective nest or opening) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KERI J. NICHOLSON whose telephone number is 571-270-3821. The examiner can normally be reached on Monday - Thursday, 8am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco, can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KJN /Keri J. Nicholson/ Examiner, Art Unit 3772 1/28/2010

/Patricia Bianco/ Supervisory Patent Examiner, Art Unit 3772